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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,654	12/21/2001	Birgit Jung	1/1178	7012
28501	7590	12/06/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,654

Applicant(s)

JUNG ET AL.

Examiner

David A Saunders, PhD

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-13 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) 21-29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-13 is/are allowed.
- 6) ☒ Claim(s) 1,7,8,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The amendment of 9/7/04 has been entered. Claims 1, 7-13 and 21-31 are pending, with claims 1, 7-13 and 30-31 under examination.

The amendment has overcome the previously stated objection to the specification and rejection under 35 USC 112, 2nd paragraph.

Applicant's amendment has necessitated the following new ground of rejection under 112.

Claims 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 31 are presented in improper English by virtue of reciting "the test system comprises" followed by a present participle ("-ing") form of an active verb. Note that the "system" is collection of cells/reagents/apparatus used by a researcher. It is the researcher, not the "system", who conducts active verb steps, such as "incubating" or "contacting".

The following prior art rejections of record are maintained.

Claims 1, 7 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al, for reasons of record.

Claims 1, 7-8 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuhrman et al, for reasons of record.

Applicant considers (page 8) that the cancellation of claim 4 (reciting "measured indirectly") has overcome the rejection. It does not, because claim 1 must still be taken as encompassing what was recited in claim 4. See specification page 2, lines 15-25,

Art Unit: 1616

which set forth the general features of the testing method; notes line 23 recites “measuring such functions directly or indirectly”.

Applicant also considers (pages 8-10) that recitation, in claim 1, that the substance is an activator or inhibitor “of an inflammatory process in which a macrophage is in a hyperactivated state due to up-regulated ARL4” sets forth a feature not taught in the prior art. The examiner notes that, while the prior art does not literally state anything about “up-regulated ARL4”, this phrase in the preamble, as well that in the conclusion “wherein the inhibitor of ARL4 is a substance which inhibits the inflammatory process”, are given no weight by the examiner for merely reciting something about “ARL4”.

It is to be noted that the “read-out” recited in claim 1 recites a “measurable read – out upon modulation of ARL4 or a biological function of ARL4” (claim 1, lines 4-5). This is an all encompassing recitation which does not require that one determine anything about ARL-4 –e.g. its level, its functional state, etc. All this states is that “ARL-4” is somehow inherently involved mechanistically, in the functioning of the “read-out” system. The “biological activity” (taken to be “biological function” of ARL-4, as defined in the paragraph spanning pages 8-9) is very broadly defined. This fact taken with the fact that the test read-out can be “indirectly” determined (page 2, line 23) indicates that, when read with its broadest reasonable meaning, claim 1 can be rejected over any art that shows a test with a “read-out” somehow related to inflammatory responses of macrophages - - e.g. the production of ROS, as in Peterson et al, or the production of H₂ O₂ and free radicals, as in Fruhman et al.

Because applicant has defined the instant "read-out" system without any definable limits, the examiner has properly applied the references of Peterson et al and Fuhrman et al.

The examiner further notes that not giving weight to the recitation of "a measurable read-out upon modulation of ARL-4 or a biological function of ARL-4" is proper; this phrase, as noted supra, does not require any detection of ARL-4 per se (e.g. its level, its functional state) but only recites that ARL-4 is somehow mechanistically involved. The instant situation, in which an underlying mechanistic basis is recited that applies to the read-out of a test system, is taken to parallel the situation in which an underlying mechanistic basis is recited that applies to a body treatment method. In such cases the CAFC has determined that stating a newly discovered mechanistic basis that explains the operative effect of a known drug does not provide for a novel method of body treatment. *Eli Lilly v. Barr Laboratories* 58 USPQ2d 1869; see page 1880.

Instantly applicant is claiming the same steps that the prior art has done; (a) some test substance is applied to a test system, which provides a readout related to the inflammatory response of macrophages, and (b) the read-out for the test substance is compared to the read-out for a control. The recitations of "ARL-4" at line 5 merely refer to the mechanistic basis for obtaining a read-out; the recitation of "ARL-4" at line 8 merely indicates a mental – step that is based upon applicant's understanding of the mechanism. Just as a scientific discovery of the mechanism underlying the action of a known drug does not impart patentability, likewise, the scientific discovery of the

Art Unit: 1616

mechanism underlying the operation of a known read-out system does not impart patentability.

Presently, new claim 31 is included in the rejection, since Peterson et al activate the macrophages used in their test system; see Example 1 at col. 8, lines 53-62. Also Fuhrman et al activate macrophages with LPS' (see example 4 at col. 8, lines 34-36) or with Zymosan (col. 8, line 41-46).

Applicant's urgings filed 9/7/04 have been considered but are unconvincing of patentability.

This application contains claims 21-29 are drawn to an invention nonelected with traverse in the reply filed on whatever filed on 11/24/03. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1616


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
December 1, 2004


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644